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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/349, 194 07/07/99 BUECHLER

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EXAMINER

GABEL, G

ART UNIT	PAPER NUMBER
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1641 11

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Offic Action Summary	Application N .	Applicant(s)
	09/349,194	BUECHLER ET AL.
	Examiner Gailene R. Gabel	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 January 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 55-96, 102-106 and 114-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 55-96, 102-106 and 114-142 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) Interview Summary (PTO-413) Paper No(s) _____.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 1/17/01 in Paper No. 10 is acknowledged and has been entered. Claims 1, 55-84, 97-101, and 107-113 have been cancelled without prejudice. Claims 85, 88, 91, 94, and 102 have been amended. Claims 134-142 have been added. Accordingly, claims 85-96, 102-106, 114-142 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 86-90, 92-93, 95-96, 103-106, 115-119, 120-123, 125-128, 130-133 and new claims 134-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 88 and 119, "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

As set forth in Paper No. 9., claims 86-87, 89-90, 92-93, 95-96, 103-106, 115-119, 120-123, 125-128, 130-133 have improper antecedent basis problems in reciting "An assay according to claim ...".

Claims 134-142 have improper antecedent basis problems in reciting "An assay according to claim ...".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. In light of Applicant's amendment, the rejection of claims 102-103 under 35 U.S.C. 102(b) as being anticipated by Bodor et al. (Clinical Chemistry, 1992) is hereby, withdrawn.
4. Claims 114-115, 119-120, 124-125, and new claims 139-141 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodor et al. (Clinical Chemistry, 1992) for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 85-93, 116-118, 121-123, 126-128, and new claims 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodor et al. (Clinical Chemistry, 1992) for reasons of record.

6. Claims 94-96 and 129-133, and new claims 137 and 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katus et al. in view of Bodor et al. (Clinical Chemistry, 1992) for reasons of record. Additionally, amended claims 102-106 and new claim 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katus et al. in view of Bodor et al. (Clinical Chemistry, 1992) for the same reason set forth in Paper No. 9 as applied to claims 94-96 and 129-133.

Response to Arguments

7. A) Applicant argues that use of indefinite article such as "An" in a dependent form is acceptable under MPEP § 608.01(n)(I)(A).

In response, the examples set forth under MPEP § 608.01(n)(I)(A) make reference to multiple dependent forms of claims which refer back, in the alternative, to more than one preceding independent or dependent claims.

B) Applicant argues that Bodor et al. fails to anticipate the instant invention because Bodor et al. does not disclose pooling antibodies with established specificities, i.e. cardiac vs. skeletal, free vs. complexed, for use in a single assay, in order to provide an antibody that binds both free and complexed cardiac specific isoforms as required in the instant claims.

In response, Bodor et al., indeed, developed monoclonal antibodies that bind cardiac specific isoforms of troponin for use in troponin immunoassays whose characterization and reactivity patterns were determined using cTnI and cTnC coated microtiter plates. The monoclonal antibodies include, 3C5.10 and 1E11.3 which are specific for only free cTnI, 5D4.1 which is specific for cTnI only when complexed with TnC, and 5 other mAbs which are specific for both free and complexed cTnI. In Table 1, Bodor summarizes antibody specificities wherein all the antibodies have specificity for binding cTnI. Bodor is, therefore, said to anticipate the instant invention and further reads on the rejected claims because the claims fail to exclude those antibodies that, likewise, have skeletal troponin reactivities.

C) Applicant argues that Bodor et al. does not suggest pooling only antibodies that bind both free and complexed cardiac specific isoforms.

In response, Bodor et al. suggest pooling antibodies and excluding those with specificities and reactivities which are not desired for certain immunoassays, such as the exclusion of 5D4.1 which recognizes both troponin I/C binary complex, but not

desired in an assay for cTnI because of its negligible reaction with cTnI in the absence of cTnC (see page 2208).

D) Applicant argues that Katus et al. fail to cure the deficiencies of Bodor et al. because Bodor et al. fail to disclose or suggest providing antibodies that bind both free and complexed antibodies. Applicant therefore contends that there is no suggestion to modify or combine the cited these cited references.

In response, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, see paragraph 8 B) which discusses Bodor et al. Katus et al. is combined thereto for his teaching of two monoclonal antibodies that are cardiac specific isoforms of TnT in an immunoassay- ELISA for cardiac Troponin T (TnT). Katus et al. characterize 1B10 and M7 as specific for cardiac specific TnT isoform and identified that 1B10 also cross-

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reacts with non-cardiac specific TnT isoform. One of ordinary skill in the art at the time of the instant invention would have reasonable expectation of success in developing and characterizing monoclonal antibodies that specifically bind free and complexed forms such as those developed and characterized by Bodor in an assay to determine both free and cardiac specific isoforms of cTnI and cTnT because Bodor specifically has shown that generation and characterization of such monoclonal antibodies are conventional and well within ordinary skill.

8. Applicant's arguments filed 2/9/01 have been fully considered but they are not persuasive. No claims are allowed.

9. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gabel 3/24/01

Gailene R. Gabel
March 24, 2001

Long

LONG V. LE
SUPERVISORY PATENT EXAMINER
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03/26/01